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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,452		Masayuki Yabuta	58777.000008	5707

21967 7590 07/09/2008

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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
07/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/030,452	YABUTA ET AL.	
	Examiner	Art Unit	
	AGNES B. ROOKE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-6,8-10,14,17,18 and 21-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6,8-10,14,17,18 and 21-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This FINAL office action is in response to the paper filed on 04/01/2008. The amendments to the claims are acknowledged.

Status of Claims

Claims 3-6, 8-10, 14, 17, 18, and 21-33 are pending and under consideration.

Rejection Withdrawn

The rejection of claims 3-6, 8-10, 14, 17, 18, and 21-36, under 35 USC 103(a), is withdrawn in view of the amendments to the claims and the evidence that Yabuta et al. do not teach the addition of 3.0 g/l of methionine to the culture medium and the addition of methionine and at least of one histidine or glycine in an amount effective to reduce byproduct formation.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 3-6, 8-10, 14, 17, 18, and 21-33 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

In the independent claims 9, 10, 17, 18, and 33, the word "byproduct polypeptide" is indefinite since examiner cannot estimate metes and bounds of

the claim, since the byproduct peptide is not defined and no examples are provided in the claims. All independent claims are included in this rejection because they do not cure the deficiencies of the independent claims by further defining the byproduct polypeptide.

Applicants responded that the specification describes the "byproduct polypeptide" as containing an O-acetylserine residue in place of serine, and that the recombinant production of hANP leads to the formation of an impurity, a byproduct polypeptide referred to as "R1." Further, Applicants state that one skilled in the art would understand the metes and bounds of the term "byproduct peptide."

Examiner responds that the production of O-acetylserine as a byproduct would be expected as part of a cysteine metabolic pathway in E.coli during the production of a protein comprising culturing E.coli host cells transformed with a plasmid capable of expressing the protein where the protein produced is a human ANP, and thus the presence of O-acetylserine cannot define the "byproduct polypeptide" itself. Further, "byproduct peptide" is not necessary an O-acetylserine residue, as it is presently claimed. In addition, inherently, the O-acetylserine will be present as the product of the metabolic pathway. Thus, the rejection stands.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 3-6, 8-10, 17, 18, and 21-31, under 35 U.S.C. 102(b) as being anticipated by Hobden et al., UK Patent Application GB 2180539,(published on April 1,1987) is maintained.

Hobden et al. teach a hybrid protein comprising a first polypeptide having human ANF. See Abstract; where the DNA mixture derived was used to transform E.coli JM103. See page 10, line 26; where the overnight culture of E.coli JM103 was diluted a hundred-fold into fresh L-broth (30 ml comprises tryptone, yeast extract and NaCl; See page 10, lines 27-28; where the yeast extract is composed of different amino acids (See "Manual of BBL Products and Laboratory Procedures, pages 293-294, please refer to the copy as it was attached to the previous office action).

Applicants responded that the manual does not teach an amount effective to reduce byproduct formation, and that example of an yeast extract is only provided to show the amounts of methionine, histidine or glycine, and that the L-

broth used by GB'539 would be insufficient to reduce the formation of byproduct polypeptide in am amount greater or equal to 50% as compared to a control medium with no methionine, histidine, or glycine.

Examiner responds that the instant claims as presented do not indicate any numerical value of the aforementioned amino acids that would be necessary to reduce the byproduct formation. Therefore, in the absence of the data in the claims, the prior art still reads on the instant claims because the necessary amino acids are used in the medium and the O-acetylserine will be present as a by product. So, in the absence of the evidence to the contrary the yeast extract and the L-broth would provide amount that would suffice byproduct formation.

Examiner maintains the rejection and applies the inherency argument because L-broth contains yeast extract, and thus will contain amino acids such as methionine, histidine, or glycine. Examiner cited the manual for laboratory procedures to show that it is understood in the prior art that the amino acids of interest are present in the L-broth formulation and thus Hobden et al. still applies. Further, claims as presented do not provide the amount of amino acids g/l that are necessary to reduce the byproduct formation. Therefore, the rejection stands.

The rejection of claims 3-6, 8-10, 17, 18, and 21-31, under 35 U.S.C. 102(e) as being anticipated by Ueda et al. (U.S. 2003/0170811 A1).

Ueda et al. teach a process for the production of alpha-human atrial natriuretic polypeptide by recombinant technology. See Abstract.

On page 9, paragraph [0112] teaches expression of a gene coding for the peptide Cla-Fused alpha-hANP (ClaH Protein); where an overnight culture of E.coli H1 containing the expression vector, plasmid pCLaHtrpSd in L-broth, where the E.coli was cultured [0113]; where the L-broth according to the "Handbook of Microbiological Media," (see page 725, as the copy was attached to the previous office action) contains yeast extract, which is composed of different amino acids.

Applicants responded that examiner's office action is insufficient to maintain the rejection because the L-broth with its amino acids does not address the issue of whether the particular amino acids are present in an amount effective to reduce byproduct formation, and that the amino acids in the yeast extract used by the '811 publication are substantially similar to that in the manual to reduce the formation of the byproduct polypeptide in an amount greater than or equal to 50% as compared to a control medium.

Examiner responds that L-broth with the yeast extract is commonly used in the art as a source of amino acids and thus the reference of Ueda et al. still applies. Further, in the instant claims as currently rejected, Applicants do not provide the amounts of amino acids that are necessary to reduce the formation of the byproduct polypeptide. Further, in the absence to the evidence to the contrary, the amount of amino acids as presented by the prior art would suffice to achieve the same effect as the amino acids in the instant claims. Therefore, the rejection stands.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

/Karen Cochrane Carlson, Ph.D./

Primary Examiner, Art Unit 1656